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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/805,125 | 03/14/2001 | Hilmar Janusson | JEK/Janusson | 4485 |

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EXAMINER
BOYD, JENNIFER A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1771 | |

DATE MAILED: 05/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) |
|------------------------------|------------------------|---------------------|
| | 09/805,125 | JANUSSON ET AL. |
| Examiner | Art Unit | |
| Jennifer A Boyd | 1771 | |

~~The MAILING DATE of this communication appears on the cover sheet with the correspondence address~~

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

THE MAILING DATE OF THIS COMMUNICATION

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 3/14/01 .

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-13, 15, 16, 18-28, 37-39 and 41 is/are pending in the application.
4a) Of the above claim(s) 33-35 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, 12, 15, 18-22, 27 and 28 is/are rejected.

7) Claim(s) 3-11, 13, 16, 23-26, 37-39 and 41 is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). _____
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) Other: _____

DETAILED ACTION***Response to Amendment***

1. The Applicant's Amendments and Accompanying Remarks, filed February 10, 2003, have been entered as Paper No. 7 and have been carefully considered. The Specification and Abstract have been amended. Claims 1 – 13, 15 – 16, 18 – 28, 37 - 39 and 41 are pending, claims 14, 17, 29 – 32, 36 and 40 are cancelled and claims 33 – 35 are withdrawn. The Examiner withdraws the 35 U.S.C. 112, 2nd paragraph rejection of claims 13, 17, 24 – 26, 29 and 30 as set forth in paragraphs 10 – 15 of Paper No. 5. Applicant's cancellation of claims 31 - 32 renders moot the 35 U.S.C. 102(b)/103(a) rejection as obvious over Stockwell (US 5,359,735) as set forth paragraphs 18 – 20 of Paper No. 5. In view of the Applicant's Arguments, the Examiner withdraws the 35 U.S.C. 103(a) rejection of claims 1 – 5, 7 - 22, 27 – 28 and 33 - 41 as being unpatentable over Klasson et al. (US 4,923,474) in view of Stockwell (US 5,359,735) in further view of Evans et al. (US 4,463,118) as set forth in paragraph 21. In view of Applicant's Arguments, the Examiner withdraws the 35 U.S.C. 103(a) rejection of claims 23 – 26 and 29 – 30 as being unpatentable over Klasson et al. (US 4,923,474), Stockwell (US 5,359,735) and Evans et al. (US 4,463,118) in further view of Ogawa et al. (US 5,658,578) as set forth in paragraph 22 of Paper No. 5. After an updated search, additional prior art was discovered that appears to render claims 1 – 2, 12, 15, 18 - 22 and 27 - 28 as currently claimed unpatentable. However, claims 3 – 11, 13, 16, 23 – 26, 37 – 39 and 41 are found to be allowable if written in independent form.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 2, 12 and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by Ishikawa et al. (US 5,733,335).

Ishikawa et al. is directed to a figure adjusting pad and process for manufacturing the same (Title). The Examiner notes that Ishikawa is drawn to a shell-shaped pads rather than prosthetic leg applications or a sleeve for a leg, but the structure set forth in the independent claim and certain dependent claims are sufficiently generic to meet the structural limitations.

As to claim 1, Ishikawa teaches a silicone gel layer 2b which may additionally contain silicone oil after curing (column 5, lines 28 – 30 and column 6, lines 42 – 66). Also, micro-balloons, equated to Applicant's "hollow microspheres", may be incorporated as a filler in the silicone gel (column 7, lines 10 – 15).

As to claims 2 and 12, Ishikawa teaches a backing sheet 3a formed by thermally bonding a knitted web S, equated to "elasticized fabric layer", of increased air-permeability to the foamed layer 2a, equated to Applicant's "second cured silicone elastomer layer", by an air-permeable hot melt 23 (column 7, lines 50 – 67). The foamed layer 2a, equated to Applicant's "second cured silicone elastomer layer", may be cured (column 7, lines 35 – 38). Due to the structure of a knitted fabric, the application of a foam would penetrate the knit to create at least a partially embedded layer.

As to claim 18, Ishikawa teaches the use of micro-balloon fillers, in particular, EXPANCEL (column 7, lines 10 – 15).

Claim Rejections - 35 USC § 102/103

4. Claims 15 and 27 – 28 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ishikawa et al. (US 5,733,335).

As to claim 15, although Ishikawa does not explicitly teach the claimed tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa, it is reasonable to presume that the tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa is inherent to Ishikawa. Support for said presumption is found in the use of like materials (i.e. composite elastic material with a cured silicone elastomer layer interspersed with hollow microspheres and an elasticized fabric layer) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 495. In addition, the presently claimed property of the tensile strength of 1 Pa and a 100% modulus of 5 to 30kPa would obviously have been present once the Ishikawa product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). In the present invention, one would have been motivated to optimize the tensile strength and modulus to assure a strong and dimensionally stable sleeve.

As to claims 27 and 28, although Ishikawa does not explicitly teach that the silicone elastomer layer has the claimed density range of 0.5 g/cm³ to 1.3g/cm³ as required by claim 27, or specifically 0.94 g/cm³ as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to

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250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28, it is reasonable to presume that claimed density range of 0.5 g/cm³ to 1.3g/cm³ as required by claim 27, or specifically 0.94 g/cm³ as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to 250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28 are inherent to Ishikawa. Support for said presumption is found in the use of like materials (i.e. a cured silicone elastomer layer containing silicone oil and microspheres) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of density range of 0.5 g/cm³ to 1.3g/cm³ as required by claim 27, or specifically 0.94 g/cm³ as required by claim 28, a tensile strength of 0.1 Pa as required by claim 27, or specifically 0.5 Pa as required by claim 28, a durometer reading of 13 – 62 as required by claim 27, or specifically 22 as required by claim 28, 100% modulus of 5kPa to 250kPa as required by claim 27, or specifically 20 kPa as required by claim 28 and compression set of 0 to 30 as required by claim 27, or specifically 8 as required by claim 28 would obviously have been present once the Ishikawa product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

5. Claims 19 - 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ishikawa et al. (US 5,733,335).

As to claims 19 and 20, Ishikawa discloses the claimed invention except for the use of microspheres having a density range of 0.005 g/cm^3 to 1.25 g/cm^3 as required by claim 19, or specifically, a density of 0.05 g/cm^3 as required by claim 20. It should be noted that increasing or decreasing the density of the microspheres is a result effective variable. As the density of microspheres increases, the cushioning of the elastomer increases. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use microspheres having a density range of 0.005 g/cm^3 to 1.25 g/cm^3 as required by claim 19, or specifically, a density of 0.05 g/cm^3 as required by claim 20, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the cushioning and strength of the microspheres which provide support to the sleeve structure.

As to claims 21 and 22, Ishikawa discloses the claimed invention except for the silicone elastomer composition containing 50 – 99.4% silicone elastomer, 0.5 – 45% silicone oil and 0.1 – 5% microspheres as required by claim 21 or specifically containing 77.25% silicone elastomer, 10% silicone oil and 0.75% microspheres as required by claim 22. It should be noted that increasing or decreasing the amount of silicone elastomer, silicone oil and microspheres are result effective variables. For example, increasing the amount of silicone would provide more elasticity to the structure, increasing the amount of silicone oil would enhance the processability of the material and increasing the amount of microspheres would increase the amount of

cushioning provided. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a silicone elastomer composition containing 50 – 99.4% silicone elastomer, 0.5 – 45% silicone oil and 0.1 – 5% microspheres as required by claim 21 or specifically containing 77.25% silicone elastomer, 10% silicone oil and 0.75% microspheres as required by claim 22, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the percentage of silicone elastomer, silicone oil and microspheres in order to provide the proper amount of cushioning and elasticity.

Allowable Subject Matter

6. Claims 3 – 11, 13, 16, 23 – 26, 37 – 39 and 41 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. While Ishikawa et al. (US 5,733,335) is believed to be the most pertinent art, it fails to teach or suggest the use of a composite elastic material comprising a cured silicone elastomer layer containing silicone oil dispersed with hollow microspheres for use as a sleeve having a closed distal end that can be rolled onto a residual limb of a prosthetic device user. Ishikawa does not teach or suggest the use of a composite elastic material as described in claim 1 in the form of a tubular sleeve open at opposed ends. Ishikawa does not teach or suggest that the elasticized fabric layer of the composite elastic material is rendered non-air permeable by a second silicone cured elastomer layer. Ishikawa does

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not teach or suggest the addition of one or more skin treatment agents blended with the silicone elastomer for use in prosthetic applications.

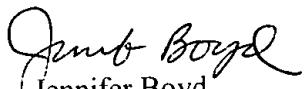
Response to Arguments

7. Applicant's arguments with respect to claims 1 – 13, 15 – 16, 18 – 28, 37 – 39 and 41 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 703-305-7082. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Jennifer Boyd
May 5, 2003


C
CHERYL A. JUSKA
PRIMARY EXAMINER